IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	**MAIL STOP APPEAL BRIEF - PATENTS**
Hisao Nishikawa et al.	)	
Application No.: 10/520,180	)	Group Art Unit: 3763
Filed: January 5, 2005	)	Examiner: LAURA A BOUCHELLE
For: INJECTION NEEDLE AND LIQUID INTRODUCING INSTRUMENT	)	Appeal No.: _____

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is from the decision of the Primary Examiner dated August 6, 2008 finally rejecting claims 1, 3-5 and 7-18, which are reproduced as the Claims Appendix of this brief.

☐ A check covering the ☐ $ 270 ☐ $ 540 Government fee is filed herewith.

☒ Charge ☐ $ 270 ☒ $ 540 to Credit Card. Form PTO-2038 is attached.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

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I. Real Party in Interest

The real party in interest for this appeal and the present application is Terumo Kabushiki Kaisha by way of an Assignment recorded in the U.S. Patent and Trademark Office at Reel 016733, Frame 0567.

II. Related Appeals and Interferences

There are no prior or pending appeals, interferences or judicial proceedings, known to Appellants, Appellants' representative, or the Assignee, that may be related to, or that will directly affect or be directly affected by or have a bearing upon, the Board's decision in the pending appeal.

III. Status of Claims

Claims 1, 3-5 and 7-18 are on appeal.

Claims 1, 3-5 and 7-18 are pending.

Claims 1, 3-5 and 7-18 are rejected.

Claims 2, 6 and 19-22 are canceled.

IV. Status of Amendments

An Amendment After Final Rejection was filed on November 5, 2008. The Advisory Action dated March 20, 2009 states that, for purposes of appeal, the Amendment After Final Rejection filed on November 5, 2008 will be entered.

V. Summary of Claimed Subject Matter

A. The Invention

The invention at issue in this application pertains to an injection needle and a liquid introducing instrument embodying an injection needle. The background portion of the present application refers to known injection needles, pointing out that they are typically quite thick hollow needles having an outside diameter between 0.3 mm and 1.2 mm. Some injection needles even have an outside diameter approaching 2 mm. Thick or large injection needles like this are problematic because they inflict pain on the patient as the needle pierces the skin. These relatively large injection needles also look quite menacing and are thus not particularly desirable for self-administered medication because individuals are reluctant to use them. For these reasons, thinner or smaller injection needles present an alternative to consider. However, thinner or smaller injection needles pose their own set of problems. In one respect, the smaller size tends to reduce the mechanical strength of the injection needle. Also, thinner injection needles necessarily have a reduced inner diameter and thus exhibit a relatively large flow passage resistance when liquid medication is injected into the living body. Hence, a

relatively considerable force must be applied to the plunger to push out the liquid medication during injection.

As discussed near the bottom of page two of the present application, and at various other places throughout the application, the injection needle that is the subject of this invention seeks to balance these competing concerns. The inventive injection needle exhibits significantly reduced pain-inducing characteristics and is not nearly as likely to intimidate and cause anxiety in patients, particularly those who self-administer medication. On the other hand, the injection needle possesses sufficient mechanical strength, and possesses a relatively small flow passage resistance so that liquid can be dispensed through the needle without having to apply a large force to the syringe plunger.

B. Mapping the Independent Claims to the Disclosure

The claims in this application include two independent claims -- Claim 1 defining an injection needle and Claim 4 reciting a liquid introducing instrument. The discussion below maps the features in each independent claim to the reference numerals in the drawing figures identifying the features and the portions of the written description describing the features.

Independent Claim 1 recites an injection needle (#1 in Fig. 1; see page 7, lines 14 and 15) comprising a puncture section (#2 in Fig. 1; see page 7, lines 14-16) having a needle point (in the proximity of #5 in Fig. 1; see page 7, lines 14-16) capable of piercing a living body (see page 7, lines 15-17), a proximal end section (#3 in Fig. 1; see page 7, lines 16 and 17) having outside and inside diameters (see Fig. 1) greater than the puncture section (#2 in Fig. 1) (see page 8, lines 1 and 2), and a tapered section (#4 in Fig. 1; see page 8, line 3) interconnecting the puncture

section (#2 in Fig. 1) and the proximal end section (#3 in Fig. 1) (see page 8, lines 3-6). The proximal end section (#3 in Fig. 1) possesses an outside diameter ranging from 0.35 mm to 1 mm (see page 11, lines 15-17). The puncture section (#2 in Fig. 1) possesses an outside diameter ranging from 0.1 mm to 0.5 mm (see page 8, lines 10-13). The length from the puncture section (#2 in Fig. 1) to the tapered section (#4 in Fig. 1) ranges from 0.2 mm to 15 mm (see page 9, lines 5-7). The length of the tapered section (#4 in Fig. 1) ranges from 1.5 mm to 10 mm (see page 9, lines 20 and 21). The total length of the puncture section (#2 in Fig. 1), the proximal end section (#3 in Fig. 1) and the tapered section (#4 in Fig. 1) to be inserted in the living body ranges from 5 mm to 40 mm (see page 9, lines 8-11 and page 10, lines 8-11). The tapered section (#4 in Fig. 1) possesses an outer profile forming an angle (letter "A" in Fig. 1) ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle (#1 in Fig. 1) (see page 9, line 23 to page 10, line 3). The tapered section (#4 in Fig. 1) provides puncture resistance smaller than the puncture section (#2 in Fig. 1) (see page 11, lines 7-14). A puncture resistance at the puncture section (#2 in Fig. 1) is 7 gf or less (see Fig. 8 and page 24, line 24 to page 25, line 3).

Independent Claim 4 defines a liquid introducing instrument (#30 in Fig. 3; see page 13, lines 19 and 20) for being mounted on a liquid inlet port (#17 in Fig. 5; see page 16, lines 5 and 6) formed on a distal end of a liquid container (#8 in Fig. 5; see page 14, lines 4 and 5) that is capable of holding a liquid therein (see page 12, lines 13-19). The liquid introducing instrument (#30 in Fig. 3) comprises an injection needle (#1 in Fig. 1; see page 7, lines 14 and 15) having a puncture section (#2 in Fig. 1; see page 7, lines 14-16) having a needle point (in the proximity of #5 in Fig. 1;

see page 7, lines 14-16) capable of piercing a living body (see page 7, lines 15-17), a proximal end section (#3 in Fig. 1; see page 7, lines 16 and 17) having outside and inside diameters (see Fig. 1) greater than the puncture section (#2 in Fig. 1) (see page 8, lines 1 and 2), and a tapered section (#4 in Fig. 1; see page 8, line 3) interconnecting the puncture section (#2 in Fig. 1) and the proximal end section (#3 in Fig. 1) (see page 8, lines 3-6). The proximal end section (#3 in Fig. 1) possesses an outside diameter ranging from 0.35 mm to 1 mm (see page 11, lines 15-17). The puncture section (#2 in Fig. 1) possesses an outside diameter ranging from 0.1 mm to 0.5 mm (see page 8, lines 10-13). The length from the puncture section (#2 in Fig. 1) to the tapered section (#4 in Fig. 1) ranges from 0.2 mm to 15 mm (see page 9, lines 5-7). The length of the tapered section (#4 in Fig. 1) ranges from 1.5 mm to 10 mm (see page 9, lines 20 and 21). The total length of the puncture section (#2 in Fig. 1), the proximal end section (#3 in Fig. 1) and the tapered section (#4 in Fig. 1) to be inserted in the living body ranges from 5 mm to 40 mm (see page 9, lines 8-11 and page 10, lines 8-11). The tapered section (#4 in Fig. 1) possesses an outer profile forming an angle (letter "A" in Fig. 1) ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle (#1 in Fig. 1) (see page 9, line 23 to page 10, line 3). A puncture resistance at the puncture section (#2 in Fig. 1) is 7 gf or less (see Fig. 8 and page 24, line 24 to page 25, line 3). The tapered section (#4 in Fig. 1) provides puncture resistance smaller than the puncture section (#2 in Fig. 1) (see page 11, lines 7-14). A base body (#6 in Fig. 3; see page 13, line 20) supports the injection needle (#1 in Fig. 1) (see page 14, lines 8-11). The puncture section (#2 in Fig. 1) and the tapered section (#4 in

Fig. 1) protrude from the base body (#6 in Fig. 3) (see Figs. 2 and 3 and page 14, lines 21-23).

The dependent claims define further features of the injection needle and the liquid introducing instrument. The specific features of the dependent claims are not at issue in this Appeal.

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are presented for review:

1) Claims 1 and 3-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,781,691 to Gross.

2) Claims 8-11 and 14-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,781,691 to Gross in view of U.S. Patent No. 7,063,681 to Peery.

3) Claims 7 and 13 are rejected as obvious under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,781,691 to Gross in view of U.S. Patent No. 5,575,778 to Hardt et al.

4) Claims 12 and 18 are rejected as obvious under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,781,691 to Gross in view of U.S. Patent No. 6,517,523 to Kaneko et al.

VII. Argument

The Final Rejection fails to establish a *prima facie* case of obviousness with respect to Claims 1, 3-5 and 7-18. In particular, the Final Rejection fails to provide sufficient evidence, supported by articulated reasoning and rational underpinning, that the combination of features recited in independent Claims 1 and 4 would have been obvious over Gross.

A. Requirement for a *Prima Facie* Case of Obviousness under 35 U.S.C. §103(a)

According to MPEP § 2142 and §2143, to establish a *prima facie* case of obviousness, there must be sufficient evidence supported by clear articulated reasoning and rational underpinning that the claimed invention would have been obvious (see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007)). The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit, and that a rejection on obviousness cannot be sustained with mere conclusory statements (*KSR* at 1396).

B. Independent Claims 1 and 4 Would Not Have Been Obvious Over Gross

There is insufficient evidence supported by articulated reasoning and rational underpinning that an injection needle possessing the combination of features recited in independent Claims 1 and 4 would have been obvious over Gross.

1. Independent Claim 1

Appellants respectfully submit that Gross fails to disclose, and would not have rendered obvious, an injection needle having the combination of features recited in independent Claim 1 including: (1) the length of the tapered section ranging from 1.5 mm to 10 mm; (2) the tapered section possessing an outer profile

forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle; (3) the tapered section providing puncture resistance smaller than the puncture section; and (4) a puncture resistance at the puncture section of 7 gf or less.

As a starting point, it is important to understand the focus of the disclosure in Gross. Gross is specifically concerned with the construction of a needle assembly for performing a spinal anesthesia procedure (see col. 2, lines 54-56). The needle is dimensioned so that that when the needle is removed from the dura mater after delivering the spinal anesthesia, a significant leakage of cerebrospinal fluid does not occur.

As shown in Fig. 2, the needle assembly includes a needle 10 having a proximal hollow hub 12, a first tubular portion 14 of uniform diameter connected to and extending distally from the hub 12, a tubular end portion 16 located distal of the first tubular portion 14 and having a smaller uniform diameter than the first tubular portion 14, and a tapered intermediate portion 18 positioned between the first tubular portion 14 and the tubular end portion 16.

With respect to feature (1), the Examiner acknowledges that Gross lacks disclosure of configuring the tapered intermediate portion 18 so that it has a length of 1.5 mm to 10 mm. The Examiner nevertheless takes the position that it would have been obvious to an ordinarily skilled artisan to configure the intermediate portion 18 of Gross's needle so that it possess the claimed length because "the goal of [Gross's] invention is to provide easy passage of the needle into human tissue" and "it would have been well within the skill of one of ordinary skill in the art to determine the optimal dimension to achieve this goal" (see page 3 of the Final Rejection).

These statements are insufficient to support the obviousness conclusion set forth in the Final Rejection. As discussed in §2143.01(IV) of the MPEP, a

> statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references (emphasis in original).

The Patent Office's Examination Guidelines for Determining Obviousness Under 35 U.S.C. §103(a) in view of *KSR International Co. v. Teleflex Inc.* state that the Examiner should clearly articulate why the claimed invention would have been obvious. For example, the Supreme Court in *KSR* held that the Examiner "must [provide] some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (*KSR* at 1396). The Supreme Court noted that an invention "composed of several elements is not proved obvious merely be demonstrating that each of its elements was, independently, known in the art" (*Id.*). To establish obviousness, it must be shown that those of ordinary skill in the art would have had some "apparent reason to combined the known elements in the fashion claimed" (*Id.*). In this case, it is not at all apparent *why* the stated modification would have been obvious to an ordinarily skilled artisan. That is, the Examiner here fails to explain, with articulated reasoning or rational underpinning, why one skilled in the art would have had reason to modify Gross's tapered intermediate portion 18 in the manner necessary to result in the claimed length.

The Examiner states near the top of page three of the August 6, 2008 final Official Action that "the goal of the invention" in Gross is to provide easy passage of

the needle into human tissue. In fact, that is not true. The second full paragraph of column two of Gross discusses the use of the disclosed needle during a spinal anesthesia procedure. In the course of this discussion, Gross comments that the "tapered intermediate portion 18 facilitates passage of the needle 10 through the body tissue." That the taper of the intermediate portion 18 makes it easier to push the needle into body tissue, as compared to a sharply angled shoulder on the intermediate portion 18, is hardly surprising. But this observation by Gross hardly qualifies as "the goal of the invention." One reason this distinction is important is the following.

The Examiner readily acknowledges Gross's shortcomings about the intermediate portion 18 -- the reference does not disclose that the intermediate tapered portion 18 possesses a length of 1.5 mm to 10 mm. The Examiner addresses this deficiency by making believe that "the goal of the invention" in Gross is to facilitates passage of the needle through body tissue. With this as the "inventive goal," it is plausible for the Examiner to argue, as she has here, that an ordinarily skilled artisan would seek to "determine the optimal dimensions" of the tapered intermediate portion 18 to achieve the "inventive goal" of facilitating passage of the needle through the body tissue.

However, as pointed out above, Gross's "inventive goal" is not to facilitate passage of the needle through the body tissue. Indeed, Gross makes only a single passing reference to the tapered intermediate portion 18 of the disclosed needle, hardly the attention one gives to the "goal of the invention." Thus, there is little basis for concluding that an ordinarily skilled artisan here would be interested in engaging in the activities that would be required to determine the "optimal dimensions" of

Gross's intermediate portion 18 for purposes of facilitating passage of the needle through body tissue.

In addition, even assuming for the sake of discussion that an ordinarily skilled artisan would have sought to determine the "optimal dimensions" of Gross's intermediate portion 18 for purposes of facilitating passage of the needle through body tissue, the Examiner has not established that the "optimal dimensions" of Gross's intermediate portion 18 for purposes of facilitating passage of the needle through body tissue would necessarily be the tapered section length specified in Claim 1 here. Indeed, carried to its logical end, the Examiner's observation about determining the "optimal dimensions" of the intermediate portion 18 for facilitating passage of the needle through body tissue would suggest a very long tapered intermediate portion 18 -- presumably, the longer the tapered intermediate portion 18, the more gradual the taper, and the easier for the tapered intermediate portion to be advanced through body tissue. But increasing the length of the intermediate portion for this purpose would mean that the length of Gross's intermediate portion 18 is outside the claimed dimension.

As discussed above, the injection needle that is the subject of the invention here seeks to balance a number of competing concerns -- avoiding an excessively thick or large injection needle that inflicts pain on the patient during usage and creates patient anxiety, while at the same time avoiding an excessively thin injection needle that possesses reduced mechanical strength and exhibits relatively large flow passage resistance. The needle here possesses features and characteristics providing a desirable balance between these conflicting/competing concerns. The length of the tapered section is one such attribute of the needle. The Examiner has

not established by any findings of fact, or other appropriate supporting evidence, that an ordinarily skilled artisan seeking to determine the "optimum" length of Gross's intermediate tapered section 18 for purposes of facilitating passage of the needle through body tissue would necessarily arrive at the length specified in Claim 1 which is developed for quite different purposes. In other words, the Examiner has not established that in the course of "optimizing" the intermediate tapered portion 18 of Gross's needle, an ordinarily skilled artisan would necessarily determine that the "optimum" length for facilitating passage of the needle through body tissue is the same as the tapered section length which the inventors here have determined results in an injection needle exhibiting a highly desirable balance between good mechanical strength and very low flow passage resistance on the one hand, and reduced patient pain and anxiety on the other hand.

The record thus does not explain why or how facilitating passage of the needle into human tissue would have led to dimensioning Gross's intermediate portion 18 so that it has a length of 1.5 mm to 10 mm. The Examiner provides no articulated reasoning or rational underpinning supporting the position that a length of 1.5 mm to 10 mm for Gross's tapered intermediate portion 18 necessarily correlates to, or would have resulted in, improved passage of the needle into human tissue. In this regard, it is likewise unclear why or how the length of 1.5 mm to 10 mm for the tapered intermediate portion 18 necessarily represents the "optimal dimensions to achieve this goal". The actual purpose of Gross's invention is to provide a needle tip 20 specifically configured and dimensioned to administer spinal anesthesia without creating significant leakage of cerebrospinal fluid when the needle is removed from the dura mater. The Examiner has not presented any evidence supporting the

position, let alone establishing, that modifying Gross's tapered intermediate portion 18 to have a length of 1.5 mm to 10 mm would "optimize" the needle's ability to pass through body tissue. According to the decision in *KSR*, simply because something could have been modified and a person of ordinary skill was capable of making the modification does not mean it would have been obvious to do so. This is especially true in the present case as no evidence has been presented establishing that the stated modification would have had the "optimizing" effect asserted by the Examiner (see MPEP §2143.01(III)).

Moreover, according to the MPEP, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation (see MPEP §2144.05(II)(B), citing *In re Antonie*, 559 F.2d 618 (CCPA 1977)). Here, there is no evidence of record that the claimed length of 1.5 mm to 10 mm would have been recognized by one skilled in the art as a result-effective variable that would have "optimized" the ability of Gross's needle to pass through body tissue.

Thus, there is insufficient evidence supported by appropriate reasoning and rational underpinning to support the position that it would have been obvious to modify Gross's tapered intermediate portion 18 to have a length ranging from 1.5 mm to 10 mm as recited in independent Claim 1. Accordingly, the rejection of Claim 1 is improper for at least those reasons and should be withdrawn.

Another aspect of the claimed injection needle not disclosed in Gross is feature (2) identified above -- the tapered section possessing an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line

parallel to a central axis of the injection needle. Addressing this point, the Examiner expresses the view that "it is well known that a reduced angle will provide a smaller puncture resistance" (see lines 9-10 of page three of the August 6, 2008 final Official Action). The attachment to the March 20, 2009 Advisory Action similarly states that "it is well known in the art that it is beneficial to reduce the puncture pressure to a minimum to make injection as painless as possible." The Examiner goes on to conclude that it would have been obvious to alter the angle of the intermediate tapered portion 18 of Gross's needle "to provide a minimum puncture pressure." Once again, the Examiner's argument misses the point.

The invention here is not solely focused on reducing puncture resistance. Rather, as discussed previously, the claimed injection needle here is specifically configured and dimensioned to take into account and address a number of divergent concerns -- the pain inflicted on patients by large or thick needles, patient anxiety associated with the use of large or thick needles, the reduced mechanical strength that is characteristic of smaller or thinner needles, and the relatively large and undesirable flow passage resistance exhibited by small or thin injection needles. Concerns about patient pain and anxiety would direct one toward the use of injection needles that are as small and thin as possible, with a relatively small inner diameter. On the other hand, concerns about the mechanical strength of the injection needle and excessively large flow passage resistance would direct one toward the use of larger or thicker needles having a larger inner diameter to reduce flow passage resistance. Thus, contrary to what the Examiner seems to imply, this is not a situation in which the degree of taper of the tapered section is based solely on the objective of reducing patient pain. Quite the contrary, the injection needle here is

configured and dimensioned to take into account a number of competing/conflicting performance concerns.

Even if there was some merit to the Examiner's simplistic view of the issue here, the Examiner's position is untenable. To succeed on this argument, the Examiner would have to establish that the angle of the tapered section recited in Claim 1 is necessarily the angle an ordinarily skilled artisan would use "to provide a minimum puncture pressure." That is, if it is the Examiner's position that it would have been obvious for an ordinarily skilled artisan to determine the taper angle for Gross's intermediate section 18 that would "provide a minimum puncture pressure," the Examiner must establish that such angle is necessarily the same as the angle recited in Claim 1. This the Examiner has not done. The record is also devoid of evidence establishing that the taper angle which would "provide a minimum puncture pressure" for Gross's intermediate portion 18 is the same as the taper angle developed by the inventors here for quite different reasons -- i.e., to impart good mechanical strength and very low flow passage resistance to the needle on the one hand, while reducing patient pain and anxiety on the other hand.

The attachment to the Advisory Action acknowledges that because the length of Gross's tapered intermediate portion 18 is not disclosed, the angle of the taper cannot be extrapolated. Thus, it is unknown whether the actual angle of the tapered intermediate portion 18 is less than or greater than the claimed angle. As an example, if the actual angle of Gross's tapered intermediate portion 18 is less than the claimed angle, there would have been no reason for one skilled in the art to modify the actual angle by *increasing* it to be equal to the claimed angle. Indeed, following the Examiner's reasoning, such a modification would adversely *increase*

puncture resistance. There is thus insufficient evidence, supported by articulated reasoning, that configuring Gross's tapered intermediate portion 18 so it possesses the claimed taper angle would have even resulted in a decrease in puncture resistance of the tapered intermediate portion 18.

The statements in the Advisory Action concerning minimizing puncture pressure so that injection is as painless as possible are problematic for other reasons as well. "It is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the principal evidence upon which a rejection was [sic - is] based" (MPEP § 2144.03 citing *In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001), "[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.").

Gross is not concerned with the puncture resistance of the tapered intermediate portion 18 and so there is no basis for assuming that an ordinarily skilled artisan would specifically seek to configure and dimension the tapered intermediate portion 18 to minimize puncture resistance. What Gross is concerned with is configuring the needle to administer spinal anesthesia without creating significant leakage of cerebrospinal fluid when the needle is removed from the dura mater. There is no findings of fact establishing that dimensioning Gross's needle to administer spinal anesthesia without creating significant leakage of cerebrospinal fluid when the needle is removed from the dura mater would necessarily result in the tapered intermediate portion 18 of Gross's needle possessing the taper angle recited in Claim 1.

Further, even if the Examiner's view about minimum puncture resistance is accepted for purposes of discussion, the rejection is still not well founded. Neither the March 20, 2009 Advisory Action nor the August 6, 2008 final Official Action provides evidence establishing what "minimum puncture resistance" means to an ordinarily skilled artisan. Accordingly, there is no evidence, supported by articulated reasoning with rational underpinning, that one skilled in the art would have been guided to modify the tapered intermediate portion 18 of Gross's needle to reduce the puncture resistance. In this regard, it is also unclear from the record what one skilled in the art would have considered "possible" in making the use of the needle "as painless as possible". That is, it is not clear from the record why or how one skilled in the art would have known whether a reduction in pain is even possible and/or by how much. Thus, the evidence of record does not support the view that the stated modification would have yielded predictable results. Therefore, it cannot be said that the stated modification would have been obvious simply because it provides predictable results. As discussed above, simply because something could have been modified, and a person of ordinary skill was capable of making the modification, does not mean it would have been obvious to do so (see MPEP § 2143.01(III)).

Thus, there is insufficient evidence supporting the Examiner's position that it would have been obvious to modify Gross's tapered intermediate portion 18 to possess an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes as recited in independent Claim 1. Accordingly, the rejection is improper and should be withdrawn for at least these reasons.

The claimed aspects of the injection needle identified as (3) and (4) above recite that the tapered section provides a puncture resistance smaller than the puncture section, and that the puncture resistance at the puncture section is 7 gf or less. In the attachment to the Advisory Action, the Examiner addresses these aspects of the injection needle at issue here by noting that the benefits of reduced puncture resistance are known in the art and that an ordinarily skilled artisan "would have the available knowledge and tools to test taper configurations to determine which provides the least puncture pressure." Once again, the Examiner's treatment of these claimed aspects of the invention does not support the obviousness conclusion.

The Examiner states that the claimed puncture resistance would have been obvious because an ordinarily skilled artisan would have the tools required to determine the configuration "which provides the least puncture pressure." However, that position presupposes that puncture resistance is a concern to Gross. In fact it is not. Gross observes in passing that the tapered intermediate section 18 facilitates passage of the needle through body tissue. But Gross does not in any way indicate that one should pay particular attention to the configuration and dimensions of the tapered intermediate portion 18 of the needle to ensure they provide the least possible puncture resistance. Indeed, there is nothing in Gross's disclosure conveying that the degree of puncture resistance of the tapered intermediate portion 18 is important. Thus, no basis exists for the Examiner's position that an ordinarily skilled artisan would specifically seek to configure and dimension the tapered intermediate portion 18 to achieve "the least puncture resistance."

In addition, the Examiner's treatment of Claim 1 improperly ignores aspects of the claimed invention. The Examiner states that it would have been obvious to configure and dimension Gross's tapered intermediate portion 18 so that is possesses "the least puncture resistance." But the Examiner does not address the language in Claim 1 referring to the puncture resistance of the tapered section relative to the puncture section -- i.e., the tapered section provides a puncture resistance *smaller than* the puncture section. Gross does not disclose that the relative puncture resistance of the tapered intermediate section 18 and the tubular end portion 16 is important and certainly does not convey that the puncture resistance of the former must be smaller than that of the latter. Indeed, based on the Gross disclosure, there is no reason for an ordinarily skilled artisan to believe that the puncture resistance of the tapered intermediate section 18 relative to the tubular end portion 16 should even be considered. Thus, there is insufficient evidence, supported by articulated reasoning with rational underpinning, that it would have been obvious to dimension and configure Gross's tapered intermediate portion 18 so that it possesses a smaller puncture resistance than the puncture resistance of the tubular end portion 16.

The Examiner states in the attachment to the March 20, 2009 Advisory Action that "it is well known in the art that it is beneficial to reduce the puncture resistance to a minimum to make injection as painless as possible." Accepting this argument as true for purposes of this discussion, it is expected that a person of ordinary skill in the art would understand the benefit associated with reducing the puncture resistance of both the intermediate section 18 and the tubular end portion 16 of Gross's needle. This would thus lead the ordinarily skilled artisan to dimension

Gross's intermediate section 18 and tubular end portion 16 so that each possesses "the least puncture resistance." Thus, the natural extension of the Examiner's reasoning would result in both the intermediate section 18 and the tubular end portion 16 of Gross's needle possessing the least puncture resistance -- i.e., the same puncture resistance. This resulting needle configuration is not what is claimed in that the intermediate portion 18 in Gross's needle would not possess a smaller puncture resistance than the tubular end portion 16.

Further, there are a variety of factors affecting the puncture resistance of the tapered section relative to the puncture section, including the angle formed by the outer profile of the tapered section relative to a line parallel to the central axis of the needle, and the length of the tapered section. For instance, Fig. 8 of the present application illustrates an increase in the puncture resistance as the needle is further advanced, thus indicating that the length of the tapered section has a bearing on the relative puncture resistance of the tapered section and the puncture section. The combination of the claimed length and angle of the tapered section recited in Claim 1 positively influences the puncture resistance of the tapered section relative to the puncture section, including the puncture resistance of the puncture section being equal to or less than 7 gf. This is explained in the specification with reference to Fig. 8, which shows a puncture resistance comparison of a needle having the claimed features and a comparative needle with a tapered section having a length of only 1 mm and a taper angle of 4 degrees, 17 minutes and 21 seconds (see the discussion at page 22, lines 11-17 and the discussion beginning at line 22 of page 23 and extending to line 4 of page 23). As shown in Fig. 8, the claimed taper section provides a puncture resistance smaller than the puncture resistance of the puncture

section. In the comparative needle, on the other hand, the puncture resistance of the taper section is larger than the puncture resistance of the puncture section. In addition, the puncture resistance of the claimed taper section is well below 7 gf, while the puncture resistance at the taper section of the comparative needle is much greater than 7 gf. Thus, the combination of the claimed length and angle of the tapered section recited in Claim 1 result in a puncture resistance of the tapered section that is less than the puncture resistance of the puncture section, with the puncture resistance of the puncture section being equal to or less than 7 gf.

Simply because "a reduced angle will provide a smaller puncture resistance" does not necessarily mean that all combinations of lengths and angles known in the art would have resulted in the claimed puncture resistance at the puncture section. As noted, Gross does not mention that puncture resistance is a concern and does not indicate that Gross's needle should be configured so that the tubular end portion 16 possesses the claimed puncture resistance. The Examiner's observation that Gross inherently discloses a puncture section having a puncture resistance of 7 gf or less is not at all supported by the evidence record. Accordingly, the rejection is improper and should be withdrawn for at least these additional reasons.

In view of the above, it is respectfully submitted that the Examiner has not presented sufficient findings of fact, and has not set forth the required articulated reasoning or rational underpinning, supporting the obviousness conclusion.

The inventors here developed an injection needle configured and dimensioned to address a number of competing/conflicting concerns exhibited by many other injection needles. These concerns include excessive patient pain and anxiety associated with the use of larger or thicker needles, insufficient mechanical

strength associated with the use of smaller or thinner needles, and undesirably large fluid flow resistance also attributable to the use of thinner or smaller needles. An injection needle having the claimed combination of features desirably possesses good mechanical strength and reduced fluid flow resistance, while also exhibiting significantly reduced patient pain and anxiety. The combination of features defining the injection needle of the present invention includes: (1) the length of the tapered section ranging from 1.5 mm to 10 mm; (2) the tapered section possessing an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to the central axis of the injection needle; (3) the tapered section providing a puncture resistance smaller than the puncture section; and (4) a puncture resistance at the puncture section being 7 gf or less.

As discussed above, these features of the injection needle are not disclosed in Gross. In addition, Gross does not seek to accomplish the same objectives achieved by the injection needle of the present invention and so it cannot be said that the claimed invention is an optimized extension of Gross's disclosure. Further, the Examiner has not established that the length, taper angle, puncture resistance and relative puncture resistance characteristics of the inventive needle here as set forth in Claim 1 are necessarily the same characteristics one would arrive at by "optimizing" relevant aspects of Gross's needle to achieve the objective described in Gross.

Reversal of the Examiner's position and withdrawal of the rejection of Claim 1 are respectfully requested.

2. Independent Claim 4

Independent Claim 4 recites a liquid introducing instrument comprising, *inter alia*, an injection needle including the features (1)-(4) discussed above with respect to independent Claim 1. Thus, for at least the reasons discussed above, the rejection of independent Claim 4 over Gross is also improper and should be withdrawn. The arguments set forth above concerning Claim 1 are incorporated herein by reference.

C. Claims 3, 5 and 7-18 Would Not Have Been Obvious Over the Combinations of Applied References

Dependent Claims 3, 5 and 7-18 incorporate the features of independent Claims 1 and 4, respectively. Thus, the subject matter recited in these dependent claims would not have been obvious over Gross, Peery, Hardt et al. and Kaneko et al. Accordingly, the rejections of these claims are improper and should be withdrawn for at least this reason.

VIII. Conclusion

For all of the reasons discussed above, it is respectfully submitted that the rejections are in error and that claims 1, 3-5 and 7-18 are in condition for allowance. For all of the above reasons, Appellants respectfully request this Honorable Board to reverse the rejections of claims 1, 3-5 and 7-18.

Respectfully submitted,

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IX. CLAIMS APPENDIX

The Appealed Claims:

1. An injection needle comprising a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than said puncture section, and a tapered section interconnecting said puncture section and said proximal end section, wherein

said proximal end section possesses an outside diameter ranging from 0.35 mm to1 mm,

said puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm,

the length from said puncture section to said tapered section ranges from 0.2 mm to 15 mm;

the length of said tapered section ranges from 1.5 mm to 10 mm;

the total length of said puncture section, said proximal end section and said tapered section to be inserted in the living body ranges from 5 mm to 40 mm;

said tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle,

said tapered section provides puncture resistance smaller than said puncture section, and

a puncture resistance at the puncture section is 7 gf or less.

3. The injection needle according to claim 1, wherein said tapered section has outer and inner profiles each having a tapered structure.

4. A liquid introducing instrument for being mounted on a liquid inlet port formed on a distal end of a liquid container that is capable of holding a liquid therein, comprising:

an injection needle having a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than said puncture section, and a tapered section interconnecting said puncture section and said proximal end section, wherein

said proximal end section possesses an outside diameter ranging from 0.35 mm to 1 mm,

said puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm,

the length from said puncture section to said tapered section ranges from 0.2 mm to 15 mm,

the length of said tapered section ranges from 1.5 mm to 10 mm;

the total length of said puncture section, said proximal end section and said tapered section to be inserted in the living body ranges from 5 mm to 40 mm;

said tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of said injection needle,

a puncture resistance at the puncture section is 7 gf or less, and

said tapered section provides puncture resistance smaller than said puncture section; and

a base body supporting said injection needle,

wherein said puncture section and said tapered section protrude from said base body.

5. The liquid introducing instrument according to claim 4, wherein said injection needle has a liquid introducing needle section that can communicate with the interior of said liquid container.

7. The injection needle according to claim 1, wherein the proximal end section includes a second needle point.

8. The injection needle according to claim 1, wherein the puncture section comprises a facet, the facet having a first ground angle with respect to the central axis.

9. The injection needle according to claim 8, wherein the first ground angle is 8.5 degrees.

10. The injection needle according to claim 9, wherein the facet comprises a slanted portion, the slanted portion having a second ground angle with respect to the central axis.

11. The injection need according to claim 10, wherein the second ground angle is 18 degrees.

12. The injection needle according to claim 1, wherein a cross-sectional angle formed between ridges of a cross-section of the needle point is 129 degrees.

13. The liquid introducing instrument according to claim 4, wherein the proximal end section includes a second needle point.

14. The liquid introducing instrument according to claim 4, wherein the puncture section comprises a facet, the facet having a first ground angle with respect to the central axis.

15. The liquid introducing instrument according to claim 14, wherein the first ground angle is 8.5 degrees.

16. The liquid introducing instrument according to claim 15, wherein the facet comprises a slanted portion, the slanted portion having a second ground angle with respect to the central axis.

17. The liquid introducing instrument according to claim 16, wherein the second ground angle is 18 degrees.

18. The liquid introducing instrument according to claim 4, wherein a cross-sectional angle formed between ridges of a cross-section of the needle point is 129 degrees.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None